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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/005,318	01/09/1998	MICH B. HEIN	310098401C1	2353

7590 03/24/2003

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EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/005,318	HEIN ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-72* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 42-72 are pending.

Applicant's election of the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site in Paper No. 31 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 42-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that they are drawn to a nonelected species, i.e., a species not encompassed by the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 31.

Claims 42-72 are being examined to the extent that they are drawn to the elected species, i.e., a species encompassed by the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site.

Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this

action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Double Patenting

Claims 42-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-23, 25-37 of U.S. Patent No. 6045774 (formerly provisionally rejected over claims of copending Application No. 08782480). Applicant argues that the present claims, as amended, do not recite the targeting molecule of the copending application. Applicant's arguments have been fully considered but they are not persuasive because the present claims have not been amended as amended in the response filed June 14, 2000 (Paper No. 12).

Claims 42-72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 22-28, 31, 65-97 of copending Application No. 08/782,481. Applicant argues that the present claims, as amended, do not recite the targeting molecule of the copending application. Applicant's arguments have been fully considered but they are not persuasive because the present claims have not been amended as amended in the response filed June 14, 2000 (Paper No. 12).

Claims 42-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-3 of U.S. Patent No. 6251392 (formerly provisionally rejected over claims of copending Application No. 08954211) and claims 1, 2, 6, 7 of U.S. Patent No. 6440419 (formerly provisionally rejected over claims of copending Application No. 09176741). Applicant argues that the present claims, as amended, do not recite the targeting molecule of the copending application. Applicant's arguments have been fully considered but they are not persuasive because the present claims have not been amended as amended in the response filed June 14, 2000 (Paper No. 12).

Claims 42-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-36 of U.S. Patent No. 6391280 (formerly provisionally rejected over claims of copending Application No. 09005167). Applicant argues that the present claims, as amended, do not recite the targeting molecule of the copending application. Applicant's arguments have been fully considered but they are not persuasive because the present claims have not been amended as amended in the response filed June 14, 2000 (Paper No. 12). Applicant argues that the biological agents are fundamentally different from imaging agents. Applicant's arguments have been fully considered but they are not persuasive. In the present claims the biological agent is an enzyme. In copending Application No. 08/782,481 the biological agent is an enzyme. In U.S. Patent No. 6045774 the imaging agent is an enzyme. Biological agents are not fundamentally different from imaging agents.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 112

Claims 42-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to or encompass a targeting molecule comprising a J chain or a portion of a J chain, wherein the J chain portion is characterized in having the ability to bind an epithelial basolateral factor.

The only structural limitations to the targeting molecule are a J chain or a portion of a J chain. However, J chains are produced and incorporated into IgA dimers or into IgM pentamers. Structural characteristics induced by the J chains in polymeric IgA and pentameric IgM constitute a specific SC-binding site. See Brandtzaeg (v32), paragraph bridging pages 78-80. The purified J chain only marginally blocks the binding of SC to dimeric IgA and IgM (Brandtzaeg (v32), at page 85, full paragraph 1). The SC-binding site depends on the incorporation of J chain into IgA or IgM polymers. There seems also to be a second requirement for the hinge region of the Fc fragment because J chain isolated from polymeric IgA does not block the binding reaction to any great extent. Also, cells containing native free J chain do not bind SC. Free J chain apparently has very low affinity for SC. The Fc portion of Ig polymers is thus essential for the SC-binding site. Apparently, J chain is unable to combine with IgG and IgD. See Brandtzaeg (v32), page 109. The available evidence speaks against a substantial affinity between free J chains and SC (Brandtzaeg (w32), page 839, paragraph bridging left and

right columns). It is more likely that the SC-binding site involves Fc structures that are generated as a result of J chain association in view of the relative inaccessibility of the J chain in the polymer structures and of the inability of the free J chain to inhibit the polymer binding SC. See Koshland (u32), page 445, full paragraph 1. In summary, although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the presence of the J chain by itself does not an SC-binding site make.

The claims are genus claims. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a J chain or portion thereof. However, as indicated above, although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the presence of the J chain by itself does not an SC-binding site make. Accordingly, a description of a J chain is not a description of the genus of targeting molecules. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claims 42-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to or encompass a targeting molecule comprising a J chain or a portion of a J chain, wherein the J chain portion is characterized in having the ability to bind an epithelial basolateral factor.

The only structural limitations to the targeting molecule are a J chain or a portion of a J chain. However, J chains are produced and incorporated into IgA dimers or into IgM pentamers. Structural characteristics induced by the J chains in polymeric IgA and pentameric IgM constitute a specific SC-binding site. See Brandtzaeg (v32), paragraph bridging pages 78-80. The purified J chain only marginally blocks the binding of SC to dimeric IgA and IgM (Brandtzaeg (v32), at page 85, full paragraph 1). The SC-binding site depends on the incorporation of J chain into IgA or IgM polymers. There seems also to be a second requirement for the hinge region of the Fc fragment because J chain isolated from polymeric IgA does not block the binding reaction to any great extent. Also, cells containing native free J chain do not bind SC. Free J chain apparently has very low affinity for SC. The Fc portion of Ig polymers is thus essential for the SC-binding site. Apparently, J chain is unable to combine with IgG and IgD. See Brandtzaeg (v32), page 109. The available evidence speaks against a substantial affinity between free J chains and SC (Brandtzaeg (w32), page 839, paragraph bridging left and right columns). In summary, Although the presence of the J chain in IgA or IgM polymers is needed in order to obtain SC binding, the presence of the J chain by itself does not an SC-binding site make.

There are no working examples in the present specification of a targeting molecule consisting solely of a J chain linked to a biological agent. There is no objective evidence in the present specification or in the prior art of record that a targeting molecule consisting solely of a J chain linked to a biological agent will function as intended. The skilled artisan is left to extensive experimentation wherein molecules comprising a J chain or protein thereof are randomly made and through trial and error experimentation is left to determine, which bind an unspecified and undefined epithelial basolateral factor. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (x32) page 1306, column 1, full paragraph 1, or Ngo (y32) page 433, full paragraph 1, and page 492, full paragraph 2.

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 48, 53, 55 are indefinite over the recitation of "comprises amino acid sequence from" because it is unclear if an amino acid sequence that is one of the SEQ ID NOs: or an amino acid sequence that is some unspecified portion of one of the SEQ ID NOs: is intended. The metes and bounds are not clearly set forth.

Claims 58, 60 are indefinite over the recitation of "comprises an amino acid sequence from" because it is unclear if an amino acid sequence that is one of the SEQ ID NOs: or an amino acid sequence that is some unspecified portion of one of the SEQ ID NOs: is intended. The metes and bounds are not clearly set forth.

Claims 42-72 are indefinite because they recite the term "specifically binds" (claim 42). Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "specifically binds" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Objections

Claim 56 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are directed to or encompass a portion of a J chain comprising a C-terminal domain. The J chain is a polypeptide. Consequently, a portion of a J chain is also a polypeptide and therefore inherently possesses a C-terminal domain.

Accordingly, claim 78 fails to further limit and does not infringe the subject matter of a previous claim.

Claims 71, 72 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claims 71, 72 the targeting molecule does not comprise IgA or IgM. In claim 42 the targeting does not comprise a full-length Ig molecule. Consequently, the targeting molecule of claim 42 inherently does not comprise IgA or IgM. Accordingly, claims 71, 72 fail to further limit and do not infringe the subject matter of a previous claim.

Claim Rejections - 35 USC § 103

Claims 42, 43, 45, 51, 52, 54-57, 59, 67, 68, 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Max (AP, cited by Applicants) and Janknecht (uu32).

Max teaches an isolated nucleic acid molecule encoding a human J chain (page 836, Figure 1) that comprises an amino acid sequence encoded by nucleotides 1-282 of SEQ ID NO: 13, as indicated below:

```
ID   IGJ_HUMAN      STANDARD;      PRT;   137 AA.
AC   P01591;
DT   21-JUL-1986 (Rel. 01, Created)
DT   01-JUL-1993 (Rel. 26, Last sequence update)
DT   15-JUL-1998 (Rel. 36, Last annotation update)
DE   IMMUNOGLOBULIN J CHAIN.
GN   IGJ OR IGCJ.
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
RN   [1]
RP   SEQUENCE FROM N.A.
RX   MEDLINE; 85159425.
RA   Max E.E., Korsmeyer S.J.;
RT   "Human J chain gene. Structure and expression in B lymphoid cells.";
RL   J. Exp. Med. 161:832-849(1985).
RN   [2]
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RP   PRELIMINARY SEQUENCE.
RX   MEDLINE; 77242318.
RA   Mole J.E., Bhown A.S., Bennett J.C.;
RT   "Primary structure of human J chain: alignment of peptides from
RT   chemical and enzymatic hydrolyses.";
RL   Biochemistry 16:3507-3513(1977).
RN   [3]
RP   DISULFIDE BONDS, AND PARTIAL SEQUENCE.
RX   MEDLINE; 93112606.
RA   Frutiger S., Hughes G.J., Paquet N., Luethy R., Jaton J.-C.;
RT   "Disulfide bond assignment in human J chain and its covalent pairing
RT   with immunoglobulin M.";
RL   Biochemistry 31:12643-12647(1992).
CC   -!- FUNCTION: SERVES TO LINK TWO MONOMER UNITS OF EITHER IGM OR IGA.
CC       IN THE CASE OF IGM, THE J CHAIN-JOINED DIMER IS A NUCLEATING UNIT
CC       FOR THE IGM PENTAMER, AND IN THE CASE OF IGA IT INDUCES LARGER
CC       POLYMERS. IT ALSO HELP TO BIND THESE IMMUNOGLOBULINS TO SECRETORY
CC       COMPONENT.
CC   ---------------------------------------------------------------------
CC   This SWISS-PROT entry is copyright. It is produced through a collaboration
CC   between the Swiss Institute of Bioinformatics and the EMBL outstation -
CC   the European Bioinformatics Institute. There are no restrictions on its
CC   use by non-profit institutions as long as its content is in no way
CC   modified and this statement is not removed. Usage by and for commercial
CC   entities requires a license agreement (See http://www.isb-sib.ch/announce/
CC   or send an email to license@isb-sib.ch).
CC   ---------------------------------------------------------------------
DR   EMBL; M12759; AAA58902.1; -.
DR   EMBL; M12378; AAA58902.1; JOINED.
DR   PIR; A01859; JIHU.
DR   SWISS-2DPAGE; P01591; HUMAN.
DR   MIM; 147790; -.
KW   Glycoprotein.
FT   MOD_RES       1      1       PYRROLIDONE CARBOXYLIC ACID.
FT   DISULFID     15     15       INTERCHAIN (WITH IG HEAVY CHAIN).
FT   DISULFID     13    101
FT   DISULFID     69     69       INTERCHAIN (WITH IG HEAVY CHAIN).
FT   DISULFID     72     92
FT   DISULFID    109    134
FT   CARBOHYD     49     49
SQ   SEQUENCE   137 AA;  15594 MW;  F55D373239EE786E CRC64;


alignment_scores:
            Quality:  493.00            Length:     93
              Ratio:  5.301               Gaps:      0
 Percent Similarity: 100.000   Percent Identity: 100.000

alignment_block:
 US-08-782-481-13 x IGJ_HUMAN   ..

 Align seg 1/1  to: IGJ_HUMAN  from: 1  to: 137

       1 GACAACAAGTGCAAGTGTGCTCGTATTACTTCTAGAATCATCCGTAGCTC 50
         ||||||||||||||||||||||||||||||||||||||||||||||||||
      10 AspAsnLysCysLysCysAlaArgIleThrSerArgIleIleArgSerSe 26

      51 AGAGGACCCAAATGAAGATATAGTCGAACGTAACATCCGTATCATCGTCC 100
         ||||||||||||||||||||||||||||||||||||||||||||||||||
      26 rGluAspProAsnGluAspIleValGluArgAsnIleArgIleIleValP 43

     101 CACTGAATAACCGGGAGAATATCTCAGATCCTACAAGTCCGTTGCGCACA 150
         ||||||||||||||||||||||||||||||||||||||||||||||||||
      43 roLeuAsnAsnArgGluAsnIleSerAspProThrSerProLeuArgThr 59

     151 CGCTTCGTATACCACCTGTCAGATCTGTGTAAGAAGTGTGATCCAACAGA 200
         ||||||||||||||||||||||||||||||||||||||||||||||||||
      60 ArgPheValTyrHisLeuSerAspLeuCysLysLysCysAspProThrGl 76

     201 GGTAGAGCTGGACAATCAGATAGTCACTGCGACTCAAAGCAACATTTGCG 250
         ||||||||||||||||||||||||||||||||||||||||||||||||||
      76 uValGluLeuAspAsnGlnIleValThrAlaThrGlnSerAsnIleCysA 93

     251 ATGAGGACAGCGCTACAGAAACCTGCTAC 279
         |||||||||||||||||||||||||||||
      93 spGluAspSerAlaThrGluThrCysTyr 102.
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Max does not teach a targeting molecule comprising a J chain linked to a biological agent.

Janknecht teaches the production of eukaryotic proteins in a functional state, using eukaryotic expression systems employing vectors designed to express either N- or C- terminally histidine tagged proteins in eukaryotic cells in order to assess their biochemical and functional

properties. The histidine tag allows the rapid enrichment of these proteins by metal chelate affinity chromatography in a native and functional state. Furthermore, the small histidine-tag is unlikely to interfere with the natural properties of the synthesized proteins. See Janknecht page 321, Abstract and paragraph bridging columns 1-2. Janknecht teaches vectors that are modified by inserting an oligonucleotide, which encodes a stretch of six His residues (paragraph bridging pages 321-322) and a method of producing the encoded protein (page 322, paragraph bridging columns 1-2). Janknecht does not teach a targeting molecule comprising a J chain linked to a biological agent.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to recombinantly express the human J chain nucleic acid molecule, as taught by Max, with a His tag, as taught by Janknecht, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because the supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in can provide a more abundant source of these polypeptides; the advantages of recombinant expression would provide a convenient source of readily purified protein that could be used for structural and/or functional studies; the histidine tag allows the rapid enrichment of these proteins by metal chelate affinity chromatography in a native and functional state. The His tagged J chain could be used in a pharmaceutical composition for the production of antibodies with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make antibodies to the His tagged J chain because the small histidine-tag is unlikely to interfere with the natural properties of the

synthesized proteins and because antibodies would allow one of ordinary skill in the art to examine the expression of the J chain protein.

The His tag is biological agent characterized in being synthesized by a cell. The metes and bounds of "derived from a cell" are not clearly set forth. The biological agent is derived from a cell in the absence of evidence to the contrary. The biological agent is capable of modifying the properties of a cell insofar as a cell that lacks a His tag has the property of lacking a His tag and a cell that has a His tag has the property of possessing a His tag. A histidine is a portion of a Ig heavy chain.

The invention is prima facie obvious over the prior art.

Claims 42, 43, 45, 51, 52, 54-57, 59, 62, 67, 68, 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Max (AP, cited by Applicants), Marston (z32), and Baxter (a32).

Max teaches an isolated nucleic acid molecule encoding a human J chain (page 836, Figure 1) that comprises an amino acid sequence encoded by nucleotides 1-282 of SEQ ID NO: 13, as discussed above. Max does not teach a targeting molecule comprising a J chain linked to a biological agent.

Marston teaches that the supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in can provide a more abundant source of these polypeptides (page 1, left column, full paragraph 1). Small polypeptides may be degraded when expressed in E. coli. Expression levels can be

improved by linking the eukaryotic gene with a bacterial gene, such as β-galactosidase, and producing a fused protein product. See page 3, right column, full paragraph 1.

Baxter teaches linking a eukaryotic gene to β-galactosidase (Examples 1 and 2, columns 6-8).

Marston and Baxter do not teach a targeting molecule comprising a J chain linked to a biological agent.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to recombinantly express the human J chain nucleic acid molecule, as taught by Max, as a fusion protein comprising β-galactosidase, as taught by Marston and Baxter, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because the supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in can provide a more abundant source of these polypeptides; the advantages of recombinant expression would provide a convenient source of readily purified protein that could be used for structural and/or functional studies; expression levels can be improved by linking the eukaryotic gene with a bacterial gene, such as β-galactosidase. β-galactosidase is an enzyme.

The invention is prima facie obvious over the prior art.

Double Patenting

Claims 42-72 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/062467. This application is undergoing pre-exam processing and is unavailable. This

rejection is being made in the event that any conflicting claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MARCH 22, 2003